

(2) Creates a record linked to the central file noting both which items a location filled and the location identity.

(3) Ensures that no item is filled by more than one location.

(4) Maintains the original order with all linked records on the central computer system.

(b) A company that has central processing of orders must assign responsibility for filling parts of orders only to registered locations that the company owns and operates.

§ 1305.25 Unaccepted and defective electronic orders.

(a) No electronic order may be filled if:

(1) The required data fields have not been completed.

(2) The order is not signed using a digital certificate issued by DEA.

(3) The digital certificate used had expired or had been revoked prior to signature.

(4) The purchaser's public key will not validate the digital signature.

(5) The validation of the order shows that the order is invalid for any reason.

(b) If an order cannot be filled for any reason under this section, the supplier must notify the purchaser and provide a statement as to the reason (*e.g.*, improperly prepared or altered). A supplier may, for any reason, refuse to accept any order, and if a supplier refuses to accept the order, a statement that the order is not accepted is sufficient for purposes of this paragraph.

(c) When a purchaser receives an unaccepted electronic order from the supplier, the purchaser must electronically link the statement of nonacceptance to the original order. The original order and the statement must be retained in accordance with § 1305.27.

(d) Neither a purchaser nor a supplier may correct a defective order; the purchaser must issue a new order for the order to be filled.

§ 1305.26 Lost electronic orders.

(a) If a purchaser determines that an unfilled electronic order has been lost before or after receipt, the purchaser must provide, to the supplier, a signed statement containing the unique tracking number and date of the lost order and stating that the goods covered by the first order were not received through loss of that order.

(b) If the purchaser executes an order to replace the lost order, the purchaser must electronically link an electronic record of the second order and a copy of the statement with the record of the first order and retain them.

(c) If the supplier to whom the order was directed subsequently receives the first order, the supplier must indicate that it is "Not Accepted" and return it to the purchaser. The purchaser must link the re-

turned order to the record of that order and the statement.

§ 1305.27 Preservation of electronic orders.

(a) A purchaser must, for each order filled, retain the original signed order and all linked records for that order for two years. The purchaser must also retain all copies of each unaccepted or defective order and each linked statement.

(b) A supplier must retain each original order filled and the linked records for two years.

(c) If electronic order records are maintained on a central server, the records must be readily retrievable at the registered location.

§ 1305.28 Canceling and voiding electronic orders.

(a) A supplier may void all or part of an electronic order by notifying the purchaser of the voiding. If the entire order is voided, the supplier must make an electronic copy of the order, indicate on the copy "Void," and return it to the purchaser. The supplier is not required to retain a record of orders that are not filled.

(b) The purchaser must retain an electronic copy of the voided order.

(c) To partially void an order, the supplier must indicate in the linked record that nothing was shipped for each item voided.

§ 1305.29 Reporting to DEA.

A supplier must, for each electronic order filled, forward either a copy of the electronic order or an electronic report of the order in a format that DEA specifies to DEA within two business days.

PART 1306—PRESCRIPTIONS

GENERAL INFORMATION

Sec.

1306.01 Scope of part 1306.

1306.02 Definitions.

1306.03 Persons entitled to issue prescriptions.

1306.04 Purpose of issue of prescription.

1306.05 Manner of issuance of prescriptions.

1306.06 Persons entitled to fill prescriptions.

1306.07 Administering or dispensing of narcotic drugs.

CONTROLLED SUBSTANCES LISTED IN SCHEDULE II

1306.11 Requirement of prescription.

1306.12 Refilling prescriptions.

1306.13 Partial filling of prescriptions.

1306.14 Labeling of substances and filling of prescriptions.

1306.15 Provision of prescription information between retail pharmacies and central fill pharmacies for prescriptions of Schedule II controlled substances.

Drug Enforcement Administration, Justice

§ 1306.05

CONTROLLED SUBSTANCES LISTED IN SCHEDULES III, IV, AND V

- 1306.21 Requirement of prescription.
- 1306.22 Refilling of prescriptions.
- 1306.23 Partial filling of prescriptions.
- 1306.24 Labeling of substances and filling of prescriptions.
- 1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.
- 1306.26 Dispensing without prescription.
- 1306.27 Provision of prescription information between retail pharmacies and central fill pharmacies for initial and refill prescriptions of Schedule III, IV, or V controlled substances.

AUTHORITY: 21 U.S.C. 821, 829, 871(b), unless otherwise noted.

SOURCE: 36 FR 7799, Apr. 24, 1971; 36 FR 13386, July 21, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

GENERAL INFORMATION

§ 1306.01 Scope of part 1306.

Rules governing the issuance, filling and filing of prescriptions pursuant to section 309 of the Act (21 U.S.C. 829) are set forth generally in that section and specifically by the sections of this part.

§ 1306.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13964, Mar. 24, 1997]

§ 1306.03 Persons entitled to issue prescriptions.

(a) A prescription for a controlled substance may be issued only by an individual practitioner who is:

(1) Authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and

(2) Either registered or exempted from registration pursuant to §§ 1301.22(c) and 1301.23 of this chapter.

(b) A prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner.

[36 FR 7799, Apr. 24, 1971, as amended at 36 FR 18732, Sept. 21, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, as amended at 62 FR 13966, Mar. 24, 1997]

§ 1306.04 Purpose of issue of prescription.

(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

(b) A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

(c) A prescription may not be issued for the dispensing of narcotic drugs listed in any schedule for "detoxification treatment" or "maintenance treatment" as defined in Section 102 of the Act (21 U.S.C. 802).

[36 FR 7799, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973, and amended at 39 FR 37986, Oct. 25, 1974]

§ 1306.05 Manner of issuance of prescriptions.

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner. Where a prescription is for gamma-hydroxybutyric acid, the practitioner shall note on the face of the prescription the medical need of the patient for the prescription. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (*e.g.*, J.H. Smith or